

PANDEMIC (H1N1) 2009 VACCINATION PROGRAM

INFORMATION FOR HEALTH PROFESSIONALS

21 SEPTEMBER 2009

The pandemic (H1N1) 2009 influenza outbreak is constantly evolving. The responses of the Australian and State and Territory Governments, health care professionals and the community are continually being reviewed and revised. The Australian Chief Medical Officer, Professor Jim Bishop, will continue to provide advice, updates and information directly to medical professionals and clinicians. These communications have been, and will continue to be, widely disseminated by the major medical peak bodies and colleges throughout the pandemic. The most current advice will be posted on the www.healthemergency.gov.au website.

PANDEMIC (H1N1) INFLUENZA VACCINATION PROGRAM

The pandemic (H1N1) 2009 vaccination program is in the final stages of preparation. The aim of the program is to provide free vaccine against pandemic (H1N1) 2009 influenza for all members of the community who wish to be vaccinated. Vaccinations are scheduled to commence 30 September 2009.

In the initial stages of the rollout of the Panvax® H1N1 vaccine, the focus will be on ensuring that people in the specified priority groups are offered the vaccine first as they are the groups who have been identified as being at highest risk from pandemic (H1N1) 2009 influenza. However, vaccination will not be restricted to those identified as being in a priority group. There will be flexibility to vaccinate other people (for example, family members of those at risk) if they wish to be vaccinated.

Currently, there is no prescribed end date for the vaccination program.

PRIORITY GROUPS FOR VACCINATION

- Pregnant women
- Children (aged 10 years and over) and adults with underlying chronic medical conditions including:
 - Chronic respiratory conditions, including asthma and COPD
 - Immunosuppression, including HIV/AIDS and use of immunosuppressive drugs
 - Cancer
 - Diabetes mellitus
 - Cardiac disease, excluding simple hypertension
 - Chronic Renal disease
 - Chronic metabolic diseases
 - Haemoglobinopathies
 - Chronic neurological diseases
- Individuals with moderate to severe obesity, BMI>35
- Health care and community care workers (including volunteers and students)
- Indigenous people (including Indigenous children aged 10 years and over) and remote and isolated communities with vulnerable people
- Children aged 10 years and over in special schools
- Parents and guardians of children aged 0 to 6 months

VACCINATION OF CHILDREN

At present, Panvax® H1N1 vaccine is not approved for use in children under the age of 10 years. Clinical trials in children have not yet been completed but information from these trials should be available towards the end of 2009.

Health professionals will be notified when the vaccine has been approved by the Therapeutic Goods Administration for use in children under the age of 10.

VACCINE DESCRIPTION

Panvax® H1N1 Vaccine is a purified, inactivated, monovalent, split virion (split virus) vaccine. A single 0.5 mL dose contains antigen of the following type:
A/California/7/2009 (H1N1) (NYMC X-179A) (A/California/7/2009 (H1N1)v-like)
15 µg haemagglutinin (HA) per dose.

Each 0.5 mL dose contains, nominally: sodium chloride 4.1 mg, sodium phosphate – dibasic anhydrous 0.3 mg, sodium phosphate – monobasic 0.08 mg, potassium chloride 0.02 mg, potassium phosphate – monobasic 0.02 mg, calcium chloride 1.5 µg and thiomersal 50 µg (for multi-dose vial presentation only).

The following are present in each 0.5 mL dose: sodium taurodeoxycholate ≤ 5 µg, ovalbumin ≤ 1.0 µg, sucrose < 10 µg, neomycin ≤ 0.7 ng, polymyxin B sulfate ≤ 0.11 ng and beta-propiolactone ≤ 1.4 ng.

Panvax® H1N1 Vaccine is prepared from influenza virus propagated in the allantoic fluid of embryonated chicken eggs.

PRESENTATION

Multi-dose vial

Each multi-dose vial contains a nominal 5 mL or 10mL of vaccine and is closed with a latex-free stopper and sealed with an aluminium crimp seal. The aluminium seal has a plastic tear-away cap attached that is removed to gain access to the vial closure. The cap is present to protect the vial closure and to indicate if the vial has been tampered with. Once removed, the cap cannot be re-affixed to the vial. The sealed units are packed into a cardboard carton. Pack size is 10 or 50 vials.

Panvax® H1N1 vaccine packed in blue boxes with blue labels contains 18 doses per 10mL vial. Panvax® H1N1 vaccine packed in red boxes with red labels contains 10 doses per 5 mL vial.

Guidelines have been developed by the Australian Technical Advisory Group on Immunisation (ATAGI) and the Royal Australian College of General Practitioners (RACGP) on how to safely handle, store and administer vaccines from multi-dose vials. A copy of the guidelines will be provided with each Vaccination Pack (VacPac) supplied by the Australian Government and will be made available online at www.healthemergency.gov.au. Further advice is available from your local Division of General Practice.

Errors in administration of the multi-dose Panvax® H1N1 vaccine should be reported to your State or Territory health department or to the TGA.

Each box of vaccine will contain stickers detailing batch number and expiry. These stickers can be affixed to consent forms and in paper patient records. They are provided to make recording of vaccine batch number easier, and are not compulsory to use.

Pre-filled syringe

Single-dose pre-filled glass syringes, complete with needle for injection, are anticipated to become available for use in young children once the TGA has approved Panvax® H1N1 for use in this age group.

CONTRAINDICATIONS

Panvax® H1N1 vaccine is contraindicated in anyone who has experienced anaphylaxis following a previous dose of any influenza vaccine, or who has experienced anaphylaxis following any vaccine component (see Vaccine Description section), including the antibiotics neomycin or polymyxin.

Panvax® H1N1 vaccine should not be used in anyone who has experienced anaphylaxis to eggs or chicken protein.

Panvax® H1N1 vaccine is not currently approved for use in children under the age of 10 years.

The Product Information for Panvax® H1N1 vaccine states that immunisation must be postponed in people who have febrile illness or acute infection.

PRECAUTIONS***Interactions with other medicines***

The immunological response may be diminished if the patient is undergoing corticosteroid or immunosuppressant treatment.

Concomitant use of other vaccines

There are no data to assess the concomitant administration of Panvax® H1N1 vaccine with other vaccines. If Panvax® H1N1 vaccine is to be given at the same time as another injectable vaccine, the vaccines should be administered at different injection sites.

DOSAGE AND ADMINISTRATION

The dose for adults and children aged 10 years and over is 15 micrograms in 0.5 mL as a single dose, usually injected into the upper arm. The vaccine should be administered by intramuscular or deep subcutaneous injection.

Panvax® H1N1 vaccine is recommended for adults and for children 10 years of age and older. Panvax® H1N1 vaccine has not been approved for children under 10 years of age at this time.

Vaccination providers will be notified once the TGA has approved Panvax® H1N1 vaccine for children under 10 years of age.

ADVERSE EVENTS***Clinical trials***

Clinical data specific to Panvax® H1N1 Vaccine show that the vaccine is safe and well tolerated in adults ≥ 18 to < 65 years of age. A total of 240 participants were administered a single dose of vaccine containing 15 µg or 30 µg HA. Data for solicited local and systemic and unsolicited adverse events for the 15 µg HA antigen dose are presented as this is the dosage to be administered.

The most common solicited local (injection-site) adverse events observed within 7 days of administration of the vaccine were injection-site tenderness, pain and induration, with the majority of reactions of mild intensity and self-limiting. The most common solicited systemic

adverse reactions were headache, myalgia and malaise, with the majority of these events mild to moderate in intensity and similarly self-limiting (see table below).

In addition, headache was identified as the most common unsolicited adverse event, reported in 11.7 % of participants. Other unsolicited adverse events, reported by more than 2 % of participants, were back pain, arthralgia, seasonal allergy, cough, oropharyngeal pain, nasal congestion, diarrhoea and toothache. There were no reports of serious adverse events.

Proportion of Adult Participants with Solicited Local and Systemic Adverse Events within 7 Days of Administration of Panvax[®] H1N1 Vaccine, Irrespective of Causality:

Solicited Adverse Event	Proportion of Participants (%) Adults (n = 120) (≥ 18 to < 65 years)
Local (injection-site)	
Tenderness	30.8
Pain	20.8
Induration	10.0
Ecchymosis	5.0
Erythema	0.8
Systemic	
Headache	25.8
Myalgia	15.8
Malaise	11.7
Fever	5.8
Nausea	5.8
Chills	0.8
Vomiting	0

Post-marketing surveillance

There are currently no post-marketing data for Panvax[®] H1N1 vaccine. It is anticipated that the adverse events after vaccination will be similar to those spontaneously reported during post-approval use of CSL's seasonal influenza vaccine, Fluvax[®] vaccine. For additional information refer to the Product Information leaflet for Panvax[®] H1N1 vaccine.

Immunisation service providers should refer to the *Australian Immunisation Handbook 9th Edition, 2008* (page 58, Post Vaccination Procedures) for complete information on the identification and management of adverse events, including anaphylaxis. The handbook is available online at www.immunise.health.gov.au

GUILLAIN-BARRÉ SYNDROME

There have been reports of a possible association with influenza vaccination and the development of Guillain-Barré syndrome (GBS). Whether this is causal or only a temporal association is unclear. Viral and bacterial infections, especially *Campylobacter jejuni* and acute respiratory tract infections are the commonest antecedents of GBS. The estimated frequency of influenza-related GBS is four to seven times higher than the estimated frequency of influenza vaccine-associated GBS. If there is a causal association with influenza vaccine it is of the order of 1-2 per million people vaccinated. During the 1976 swine influenza vaccination campaign in the USA, about 10 persons per million vaccinated persons developed GBS. The reason why GBS developed in association with that specific vaccine has never been firmly established. Manufacturing processes for influenza vaccines have been significantly improved since then.

THIOMERSAL

Panvax® H1N1 vaccine has been formulated in multi-dose vials containing the preservative, thiomersal. Thiomersal, which contains a small amount of mercury, has been used in medical products and vaccines for more than 60 years and is the most commonly used preservative in multi-dose vials. It has a very long safety record. Thiomersal was removed from vaccines given to young children in Australia as a precaution to reduce the theoretical risk of exposure to mercury in babies, particularly those of very low birth weight. However, there is no evidence that thiomersal in vaccines has caused any developmental or neurological abnormalities, such as Attention Deficit Hyperactivity Disorder (ADHD), autism or any other health problem.

Following a recent review of the evidence, ATAGI has advised that influenza vaccines containing thiomersal are considered safe. Full details of ATAGI's advice will be made available on the www.healthemergency.com.au website in the near future.

ADVERSE EVENT REPORTING

Immunisation service providers should report all adverse events, whether serious or unexpected, following pandemic (H1N1) 2009 influenza vaccination just as they would report similar events associated with any other vaccine. In most States and Territories, there is a requirement that serious or unexpected adverse events be notified to the relevant health authority. In Tasmania, reports should be made directly to the Therapeutic Goods Administration (TGA).

For the pandemic (H1N1) 2009 influenza vaccination program, immunisation service providers may also elect to report directly to TGA. Information provided to TGA will be passed on to the State and Territory health authorities for any necessary follow up to be undertaken.

Reporting to the TGA:

- Online at <http://www.tga.gov.au> ;or
- through the "Blue Card" form which is available on the TGA website at <http://www.tga.gov.au/adr/bluecard.htm>

Reporting can also be made via the Pandemic Hotline on 180 2007.

What adverse events should be reported?

Any adverse event that the immunisation service provider considers to be serious or unexpected should be reported. Serious adverse events are listed in Appendix 6 of the *Australian Immunisation Handbook 9th Edition*

<http://www.health.gov.au/internet/immunise/publishing.nsf/Content/handbook-appendix6>

Can patients report adverse events?

Patients wanting to report an adverse event can do so by submitting a report online directly to the Therapeutic Goods Administration at www.tga.gov.au, or by calling the Pandemic Hotline on 180 2007.

VACCINE ORDERING

Panvax® H1N1 vaccine will be distributed via the usual ordering and distribution processes used for other vaccine supplies as part of the National Immunisation Program. Panvax® H1N1 vaccine is ordered through your usual State or Territory health department contact for ordering vaccines.

VACCINATION PACKS

To ensure immunisation service providers have sufficient resources to administer the Panvax® H1N1 vaccine, the Australian Government will be making vaccination packs (VacPacs) available to all providers. Different VacPacs are being assembled for use in two settings:

1. Small VacPacs for use in General Practices (including Aboriginal Medical Services)
2. Large VacPacs for use in hospitals and large vaccination centres.

The contents are being provided from the National Medical Stockpile and in accordance with the *Australian Immunisation Handbook 9th Edition 2008* which can be viewed online at <http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-home>

An information sheet detailing the contents of the VacPacs will be provided inside each VacPac. All VacPacs will contain sufficient equipment to assist with the administration of 200 doses of Panvax® H1N1 vaccine. Some additional quantities of each component will be provided to cover normal levels of wastage that may occur.

Please note that the Panvax® H1N1 vaccine will be provided separately to the VacPacs. However, both the vaccine and the VacPacs can be ordered through your usual State or Territory health department contact for ordering vaccines.

ADDITIONAL INFORMATION TO ACCOMPANY THE VACCINE

Additional printed material will be made available to all immunisation service providers with each order of the vaccine.

Vaccination consent form

The Australian Government has produced a Panvax® H1N1 vaccination consent form. The use of the consent form is not a requirement for the purposes of the pandemic (H1N1) 2009 vaccination program. Vaccine providers are advised to have regard to their usual informed consent procedures applicable to the use of vaccines that are registered for use by the TGA. A vaccination consent form can be provided with each dose of vaccine ordered. Please advise your State or Territory health department if you will not be using consent forms or do not require ongoing delivery of consent forms with each order of vaccine placed.

Vaccine recipient information sheet

The Australian Government has also produced a 'take home' information sheet for vaccine recipients. The information sheet contains information on vaccination of people in priority groups, adverse events post vaccination and the management and reporting of adverse events. One copy of the information sheet will be provided with each dose of vaccine ordered.

Guidelines for the use of multi-dose vials

Guidelines have been developed by the Australian Technical Advisory Group on Immunisation and the Royal Australian College of General Practitioners on how to safely handle, store and administer vaccines from multi-dose vials. A copy of the guidelines will be provided with each vaccine order. The guidelines are also available online at www.healthemergency.gov.au. Further advice is available from your local Division of General Practice.

Product information leaflet

The Panvax® H1N1 vaccine manufacturer, CSL Limited, will provide a copy of the vaccine product information leaflet with each box of vaccine.

VacPac contents sheet

Both large and small VacPacs will contain a contents sheet for that type of VacPac.

USEFUL CONTACT INFORMATION

General information on pandemic (H1N1) 2009 influenza or the Panvax® H1N1 vaccine

www.healthemergency.gov.au

Pandemic Hotline 180 2007

Ordering Panvax® H1N1 vaccine and VacPacs

State or Territory health department

Panvax® H1N1 vaccine adverse events reporting

www.tga.gov.au

Pandemic Hotline 180 2007

State or Territory health department

State and Territory contact points for vaccine related information

WA: 1800 243 522 or www.public.health.wa.gov.au

SA: call 08 8226 7177 or visit www.flu.sa.gov.au

VIC: call: 1300 882 008 or visit www.humanswineflu.health.vic.gov.au

TAS: call 1800 358 362 (1800 FLU DOC) or www.pandemic.tas.gov.au

ACT: 02 6205 2300 or www.health.act.gov.au and click on Health Professionals

NSW: visit www.emergency.health.nsw.gov.au/swineflu/vaccination/index.asp, or

call your local Public Health Unit

(www.health.nsw.gov.au/publichealth/infectious/phus.asp)

QLD: Your local Population Health Unit

NT: call 08 89228044 or visit www.H1N1vaccine.nt.gov.au